Notice of Allowability	Application No.	Applicant(s)	
	10/771,259	HARMENBERG ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment dated 10/18/2005*.

2. ☒ The allowed claim(s) is/are *2,4,5,7-10,13-16,18,20,21,23-25,27-31,33-36 and 40*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *11/03/05* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Gorman on 11/03/2005.The following changes have been made:

See attachment.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

ATTACHMENT: EXAMINER"S AMENDMENT SHOWING ALL CHANGES FROM ORIGINAL PATENT CLAIMS

1. Canceled

2. A pharmaceutical composition for topical administration to treat recurrent herpes infections comprising, as sole active drug substances, a [synergistic] combination of an [topically acceptable] antiviral ingredient [substance] selected from the group consisting of foscarnet, acyclovir, [cidofovir, desciclovir, famciclovir, ganciclovir, lobucavir,] penciclovir, [PMEA, valacyclovir, 2242, PAA, PFA] and 9-[4-hydroxy-2-(hydroxymethyl)butyl]guanine (H2G), or a[n ester,] salt [or solvate] thereof and an antiinflammatory glucocorticoid ingredient selected from the group consisting of hydrocortisone and esters thereof, in a pharmaceutically acceptable carrier, wherein said combination of antiviral and glucocorticoid is more effective in treating said herpes infections than either ingredient alone.

3. Canceled

4. [A] The pharmaceutical composition according to claim 2, wherein the antiinflammatory glucocorticoid is [selected from the group consisting of] hydrocortisone[, alclometasone, desonide, fluprednidene, flumethasone, hydrocortisone butyrate, clobetasone, triamcinolone acetonide, betamethasone, budesonide, desoximethasone, diflorosane, fluocinolone, fluocortolone, fluticasone, methylprednisolone aceponate, mometasone and rofleponide or an ester, salt or solvate thereof].

5. [A] The pharmaceutical composition according to claim [1]2, wherein the antiviral [substance] is foscarnet and the antiinflammatory glucocorticoid is hydrocortisone[, or an ester thereof].

6. Canceled

7. A pharmaceutical composition according to claim [1]2, wherein the antiviral [substance] is acyclovir, [or an ester, salt or solvate thereof,] and the antiinflammatory glucocorticoid is hydrocortisone[, or an ester thereof].

8. The pharmaceutical composition according to claim 5 [comprising] wherein said foscarnet is contained in an amount of 0.1-10% (w/w) [foscarnet] and said hydrocortisone is contained in an amount of 0.005-3% (w/w) based on the weight of the pharmaceutical composition [hydrocortisone].

9. The pharmaceutical composition according to claim 8 [comprising] wherein said foscarnet is contained in an amount of 1-5% (w/w) based on the weight of the pharmaceutical composition [foscarnet].

10. The pharmaceutical composition according to claim 8 [comprising] wherein said foscarent is contained in an amount of 0.3-3% (w/w) [foscarnet] and said hydrocortisone is contained in an amount of 0.25-1% (w/w) based on the weight of the pharmaceutical composition [hydrocortisone].

11. Canceled

12. Canceled

13. The pharmaceutical composition according to claim 7 [comprising] wherein said acyclovir is contained in an amount of 0.1-10% (w/w) [acyclovir] and said hydrocortisone is contained in an amount of 0.005-3% (w/w) based on the weight of the pharmaceutical composition [hydrocortisone].

14. The pharmaceutical composition according to claim 13 [comprising] wherein said acyclovir is contained in an amount of 1-5% (w/w) based on the weight of the pharmaceutical composition [acyclovir].

15. The pharmaceutical composition according to claim 14 [comprising] wherein said hydrocortisone is contained in an amount of 0.25-1% (w/w) based on the weight of the pharmaceutical composition [hydrocortisone].

16. A cream, lotion, gel, ointment, plaster, stick or pen containing a pharmaceutical composition according to any one of claims 2, 4, 5, 7-10 and 13 [1]-15.

17. Canceled

18. A method for treating recurrent [the prophylaxis and/or treatment of] herepesvirus infections of the skin or mucous membranes in mammals having or identified as being at risk of developing said infections comprising topically administ[ration]ring thereto, as sole active drug substances and in combination or in sequence,[a therapeutically synergistic dose of] an [topically acceptable] antiviral [substance] ingredient selected from the group consisting of foscarnet, acyclovir, [cidofovir, desciclovir, famciclovir, ganciclovir, lobucavir,] penciclovir, [PMEA, valacyclovir, 2242, PAA, PFA] and 9-[4-hydroxy-2-(hydroxymethyl)butyl]guanine (H2G), or a[n ester,] salt [or solvate] thereof and an antiinflammatory glucocorticoid ingredient selected from the group consisting of hydrocortisone and esters thereof, in a pharmaceutically acceptable carrier, wherein said antiviral and glucocorticoid are more effective in treating said herpesvirus infections than either ingredient alone.

19. Canceled

20. [A] The method according to claim 18, wherein the antiinflammatory glucocorticoid is [selected from the group consisting of] hydrocortisone[, alclometasone, desonide, fluprednidene, flumethasone, hydrocortisone butyrate, clobetasone, triamcinolone acetonide, betamethasone, budesonide, desoximethasone, diflorosane, fluocinolone, fluocortolone, fluticasone, methylprednisolone aceponate, mometasone and rofleponide or an ester, salt or solvate thereof].

21. A method according to claim 18[17], wherein the antiviral [substance] is foscarnet and the antiinflammatory glucocorticoid is hydrocortisone, or an ester thereof.

22. Canceled

23. A method according to claim 18[17], wherein the antiviral [substance] is acyclovir, [or an ester, salt or solvate thereof], and the antiinflammatory glucocorticoid is hydrocortisone, or an ester thereof.

24. A method for [the prophylaxis and/or treatment of] treating recurrent herpes virus infections of the skin or mucous membranes in mammals having or identified as being at risk of developing said infections comprising topically administ[ration]ring thereto a therapeutic dose of a topically acceptable composition according to any one of claims [1-]2, 4, 5, 7-10 and 13-15.

25. A method according to claim 24 wherein the composition is contained in a cream, lotion, gel, ointment, plaster, stick or pen.

26. Canceled

27. A method according to any one of claims [17-]18, 20, 21 and 23, wherein the antiviral [substance] and the glucocorticoid are administered 1 to 10 times per day.

28. A method according to claim 27, wherein the antiviral [substance] and the glucocorticoid are administered 3 to 4 times per day.

29. A method according to claim [26]40, wherein the antiviral [substance] and the glucocorticoid are administered 1 to 10 times per day.

30. A method according to claim 29, wherein the antiviral [substance] and the glucocorticoid are administered 3 to 4 times per day.

31. A method according to any one of claims [17-]18, 20, 21 and 23 wherein the antiviral [substance] and the glucocorticoid are administered in combination and are contained in a cream, lotion, gel, ointment, plaster, stick or pen.

32. Canceled

33. A method according to claim 24, wherein the antiviral [substance] and the glucocorticoid are administered 1 to 10 times per day.

34. A method according to claim 33, wherein the antiviral [substance] and the glucocorticoid are administered 3 to 4 times per day.

35. A method according to claim 31, wherein the antiviral [substance] and the glucocorticoid are administered 1 to 10 times per day.

36. A method according to claim 35, wherein the antiviral [substance] and the glucocorticoid are administered 3 to 4 times per day.

37. Canceled

38. Canceled

39. Canceled

40. The method according to claim 18, wherein said antiviral is acyclovir and said anti-inflammatory glucocorticoid is hydrocortisone.